THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	C.A. No. 09-184-LPS **PUBLIC VERSION**
MYLAN PHARMACEUTICALS INC., Plaintiff, v. GALDERMA LABORATORIES INC., GALDERMA LABORATORIES, L.P., and SUPERNUS PHARMACEUTICALS, INC., Defendants.	C.A. No. 10-892-LPS

MYLAN'S RESPONSIVE POST-TRIAL BRIEF REGARDING REMEDY

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

CASES

STATUTES

RULES

TABLE OF ABBREVIATIONS

"Amin patents"	Refers collectively to U.S. Patent Nos. 5,789,395 and 5,919,775
"Ashley patents"	Refers collectively to U.S. Patent Nos. 7,211,267 and 7,232,572
"D.I. 892-X"	Refers to a docket entry in Case No. 10-892-LPS
"D.I. 184-X"	Refers to a docket entry in Case No. 09-184-LPS
"Galderma"	Refers to collectively to Plaintiffs the Research Foundation of State University of New York and New York University; Plaintiffs and Declaratory Judgment Defendants Galderma Laboratories Inc., and Galderma Laboratories, L.P.; and Declaratory Judgment Defendant Supernus Pharmaceuticals, Inc.
"Mauro Decl."	Refers to the Declaration of Anthony Mauro
"Mylan"	Refers to Defendant and Declaratory Judgment Plaintiff Mylan Pharmaceuticals Inc.
"Nelson Decl."	Refers to the Declaration of Philip B. Nelson, Ph.D.
"Paragraph IV"	Refers to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)
"Section 271"	Refers to 35 U.S.C. § 271
"532 patent" / "Chang patent"	Refers to U.S. Patent No. 7,749,532

I. INTRODUCTION

Galderma failed to meet its burden of justifying a permanent injunction under the *eBay* factors. Under the circumstances present here, the "principles of equity" require denial of any injunctive relief. Moreover, Galderma's request for relief under Section 271(e) is contradicted by the facts, law and Galderma's own pleading. Neither party in Case No. 10-892 (which pertains only to the Chang patent) alleged a claim or requested relief under Section 271(e)(2). Even if Galderma had met the pleading requirement, Section 271(e)(2) would still not apply because Mylan's Paragraph IV certification does not include the Chang patent.

II. GALDERMA IS NOT ENTITLED TO A PERMANENT INJUNCTION

Galderma is not entitled to a permanent injunction because it has failed to meet its burden of proof under the *eBay* factors.[1] Galderma's arguments are premised on the fact that there has been no generic introduction into the market for Oracea® and as a result, Galderma concludes that it would be harmed if Mylan is now permitted to launch its ANDA product. [redacted] "A violation of the right to exclude does not inevitably lead to the conclusion that a patent holder cannot be adequately compensated by remedies at law such as monetary damages without first applying the principles of equity." *z4 Techs., Inc. v.*

[1] Even if it was entitled to relief under Section 271(e), which (as discussed below) it is not, Galderma's request for an injunction under Section 271(e)(4)(B) must still be denied because Galderma failed to carry its burden. *See Alcon, Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 06-234-SLR, 2010 WL 3081327, at *3 (D. Del. Aug. 5, 2010) (denying relief under § 271(e)(4)(B) where patentee failed to prove permanent injunction was appropriate under the *eBay* factors).

Microsoft Corp., 434 F. Supp. 2d 437, 441 (E.D. Tex. 2006) (denying permanent injunction).

[redacted] Under the circumstances present here, it would be inequitable to extend that protection.

A. Galderma's Alleged Irreparable Harm Is Calculable and Can Be Compensated by Monetary Damages

Galderma repeats the same arguments (and supporting declarations) that it advanced in support of a preliminary injunction, namely, lost market share, price erosion, loss of goodwill and the reduction of investments and employees. D.I. 184-283; § III.B.1. Galderma's rehashing is not "sufficient proof vis-à-vis the broad scope of the relief requested." *Praxair, Inc. v. ATMI, Inc.*, 479 F. Supp. 2d 440, 443 (D. Del. 2007). In *Praxair*, the court refused to enter a permanent injunction where the patentee failed to "iterate specific reasons why [defendant's] infringement cannot be compensated for with a money award," and found that the patentee had "not explained why it may have 'difficulties calculating damages going forward,' nor how money damages could not adequately compensate for 'lost market share' or any 'lost research opportunities.'" *Id.* at 444. Galderma similarly failed to make a clear showing of irreparable harm.

[redacted] The *King* court further acknowledged that "courts have routinely decided that market share and price erosion do not amount to irreparable harm." *Id.*; *see also Eli Lilly & Co. v. American Cyanamid*

Co., 82 F.3d 1568, 1578 (Fed. Cir. 1996) (affirming denial of preliminary injunctive relief and noting district court's finding that "calculating lost profits would be a relatively simple task").

Similarly, in *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, C.A. No. 05-CV-1887 (DMC), 2007 WL 2669338, at *14 (D.N.J. Sept. 6, 2010), the court held that "[b]oth loss of market share and price erosion are economic harms and are compensable by money damages."

[redacted] "[T]he court [is] not swayed by the fact that money damages may be difficult to calculate. . . . Specifically, in the context of generic competition in the pharmaceutical industry, some courts have held that loss of market share is a compensable economic injury." *Id.*

B. The Balance of Hardships and The Public Interest Weigh Against a Permanent Injunction

As to the remaining *eBay* factors, Galderma argues only that Mylan will not be harmed because it has no right to sell its product in view of the Chang patent and that the public has an interest in upholding patents and encouraging the development of pharmaceuticals. D.I. 184-283 at 10. [redacted] A permanent injunction would only force the public to continue paying monopoly prices, leaving the public with no right of recourse. Whereas, absent a permanent injunction, any harm to Galderma could be compensated by a royalty. Thus, these factors also weigh against a permanent injunction. *See*

Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., No. C95-03577-DLJ, 2008 WL 4647384, at *10 (N.D. Cal. Oct. 20, 2008) (declining to amend an injunction to conform with a one-year *de facto* patent extension granted by the PTO because the balance of hardships weighed in the defendant's favor: "the greater loss would be the inability [of defendant] to enter and establish a position based on a state-of-the-art product" in an important market).

III. GALDERMA IS NOT ENTITLED TO ANY RELIEF UNDER 35 U.S.C. § 271(e)

Galderma is not entitled to ***any*** relief under Section 271(e)(4)(A) and/or (B) because Mylan's declaratory judgment action regarding the Chang patent did not arise from a claim for infringement under Section 271(e)(2). Mylan did not request declaratory judgment under Section 271(e). D.I. 892-1. And, in its answer and counterclaims, Galderma alleged infringement of the Chang patent "under [Section] 271(a), (b) and/or (c)" – ***not under Section 271(e)***. D.I. 892-15 at ¶ 49. The fact that neither Mylan nor Galderma pleaded a claim for infringement under Section 271(e)(2) as to the Chang patent is dispositive.

Even if Galderma had requested relief under Section 271(e), which it did not, that request would have been legally impermissible because a Paragraph IV certification for the Chang patent is a necessary predicate to a claim under Section 271(e). The court in *Eisai Co., Ltd. v. Mutual Pharm. Co.*, C.A. No. 06-3613 (HAA), 2007 WL 4556958, at *12 (D.N.J. Dec. 20, 2007), squarely addressed this issue. There, the defendant filed a Paragraph IV certification against four patents, but the patentee attempted to sue under Section 271(e)(2) based on a fifth patent that was not included in the certification. The court dismissed the patentee's Section 271(e)(2) suit as to the fifth patent because the ANDA did not contain a certification for that patent. The court held, "to establish an act of infringement pursuant to § 271(e)(2), the ANDA must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question." *Id.* at *12. The *Eisai* court explained that "in several opinions, the Federal Circuit has provided detailed

explanations of the workings of the Hatch-Waxman Act and the ANDA process." *Id.* at *11. "These recitations make clear that, according to the Federal Circuit, § 271(e)(2) depends upon the filing of an ANDA containing a Paragraph IV certification." *Id.* (noting Federal Circuit precedent "explicitly described the statute as 'referring to an ANDA containing a paragraph IV certification'" and recited, "the Hatch-Waxman Act gives a drug patent owner the right to bring an action for infringement *upon the filing of a paragraph IV certification*") (quoting *Bristol-Myers Squibb Co. v. Royce Labs., Inc*, 69 F.3d 1130, 1131 (Fed. Cir. 1995)). Here, Mylan did not file a paragraph IV certification as to the Chang patent, nor was it obligated to do so (*see* 21 C.F.R. 314.94(a)(12)(viii)(C)(2)); thus, there can be no infringement under Section 271(e)(2).

None of the cases cited by Galderma compel a different conclusion.[2] Unlike Mylan, the defendants in *Glaxo* and *Impax* filed counterclaims for declaratory judgment of no infringement under Section 271(e)(2). *See Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004); *Impax Labs, Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1373 (Fed. Cir. 2006). The facts in the *Glaxo* and *Teva* cases are also distinguishable because the applications were filed under 21 U.S.C. § 357, "a now-repealed provision of the Federal Food, Drug and Cosmetic Act relating to antibiotics," which did not require Paragraph IV certification. *Glaxo Group*, 376 F.3d at 1344; *see also Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 828-829 (N.D. Ill 2004).

IV. CONCLUSION

Mylan therefore requests that the Court deny Galderma's requested relief.

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[2] Galderma's reliance on *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367 (Fed. Cir. 2008) is equally misplaced. There, the court considered whether the district court retained jurisdiction under Section 271(e)(2) after a patent expires and stated, "*[i]f the applicant provides a Paragraph IV certification*, the patent holder may file suit under Section 271(e)(2)(A)." Similarly, the Court in *Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 111 (D.D.C. 2004), also cited by Galderma, clarified that "[u]nder the Hatch-Waxman amendments, filing an ANDA *with a paragraph IV certification* is deemed to be a 'highly artificial' act of infringement." Neither case supports the conclusion Galderma seeks – that an action under Section 271(a), (b), or (c) can be converted *ex post facto* into a claim for relief under Section 271(e).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on September 14, 2011, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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